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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/762,081  | 01/20/2004  | Stuart B. Levy       | PKZ-013CPCN         | 4614             |
| 959   | 7590        | 01/14/2005           | EXAMINER            |                  |
| LAHIVE & COCKFIELD, LLP.<br>28 STATE STREET<br>BOSTON, MA 02109 |             |                      | BADIO, BARBARA P    |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1616                |                  |

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/762,081

Applicant(s)

LEVY ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 4-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 7, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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**First Office Action on the Merits**

***Election/Restrictions***

1. Applicant's election without traverse of Group I in the reply filed on November 16, 2004 is acknowledged.

2. Claims 1-7, 29 and 30 are pending in the present application. Based on applicant's elected species, claims 2 and 4-6 stand withdrawn from further consideration as being drawn to a nonelected species. Claims 1, 3, 7, 29 and 30 stand rejected as indicated below.

Note: The definition of R<sub>2</sub> in Claim 2 does not include an acyloxy group as defined by the elected species.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernardi et al. (US 3,901,942).

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Bernardi et al. teach a generic group of 5,9-substituted tetracycline derivatives, including 9-t-butyl-6-deoxy-5-hydroxytetracycline (see the entire article, especially col. 1, formula II; col. 10, Examples 10 and 11). The reference teaches the compounds are useful as chemotherapeutic agents and in the preparation of 7-substituted tetracycline derivatives (col. 1, lines 60-64). The compounds and compositions taught by the reference are encompassed by the instant claims.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3, 7, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernardi et al. (US 3,901,942).

Bernardi et al. teach a generic group of 5,9-substituted tetracycline derivatives, including 9-t-butyl-6-deoxy-5-hydroxytetracycline (see the entire article, especially col. 1, formula II; col. 10, Examples 10 and 11). The reference teaches the compounds are useful as chemotherapeutic agents and in the preparation of 7-substituted tetracycline derivatives (col. 1, lines 60-64).

The instant claims differ from the reference by reciting additional tetracycline derivatives not exemplified by the reference. However, the reference teaches R<sub>1</sub> can be

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an acyloxy having 1 to 4 carbon atoms (see col. 1, lines 32-34). Therefore, it would have been obvious to the skilled artisan in the art at the time of the invention to make any of the species of the genus taught by reference, including those of the instant claims, with the reasonable expectation that said compound(s) would have similar properties and, thus, the same use as the genus as a whole. The motivation would be based on the desire to make additional compounds as taught by the reference for use as chemotherapeutic agent as taught by Bernardi.

### ***Telephone Inquiry***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

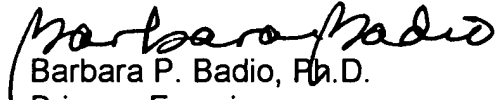
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB

January 10, 2005